



wherein **said agent is selected from the group consisting of** membrane stabilizer, cross-linker, and cell lysis inhibitor.

132. The method of claim 60, wherein said cell lysis inhibitor is selected from glutaraldehyde, formaldehyde and formalin.

Claim 55 includes both open language (“comprising”) and closed language (“consisting of”). The claim recites a sample that comprises (i.e., includes) free fetal DNA and an agent that inhibits cell lysis. That agent is selected from the group consisting of membrane stabilizer, cross-linker, and cell lysis inhibitor. This claim language, which is known as a Markush group, limits the agent to only one of the recited options: membrane stabilizer, cross-linker, and cell lysis inhibitor (hereinafter the “Markush options”).

The flaw of Natera’s argument is that the claim is not limited to only one agent that inhibits cell lysis. In accordance with the plain and ordinary meaning of “comprising,” the sample can include more than one agent. Thus, a sample with an agent that inhibits cell lysis selected from the Markush options is within the scope of the claims even if the sample includes other agents that inhibit cell lysis. As a simple example, a sample with free fetal DNA and a first cell lysis inhibitor (e.g., glutaraldehyde) is within the scope of the claims because the sample includes free fetal DNA and a cell lysis inhibitor agent. If a second cell lysis inhibitor agent (e.g., allantoin) is added to the sample, it is still within the scope of the claims because the open language of the claims (“said sample comprises”) allows the sample to include additional components, including a second cell lysis inhibitor agent.

Natera accuses Ravgen of using the “comprising” language to reopen the closed Markush group. Dkt. 425 at 1. Instead, Natera is using the closed Markush group to close the open “comprising” language. Under the proper construction, the Markush group is closed (i.e., at least

one agent is limited to one of the Markush group options) while the components that compromise the sample are open (i.e., can include more than one agent).

The Federal Circuit considered a similar issue in *Amgen, Inc. v. Amneal Pharm. LLC*, 945 F.3d 1368 (Fed. Cir. 2020). The claim at issue recited a pharmaceutical composition comprising a Markush group of binders and a Markush group of disintegrants. *See id.* at 1371. The Court found the Markush groups to be closed but the “comprising” portion of the claim to include additional binders and disintegrants. *See id.* at 1378-79. “The term ‘comprising’ is the standard transition term used to make clear that the claim does not preclude the presence of components or steps that are in addition to, though not inconsistent with those recited in the limitations that follows.” *Id.*

Natera’s reliance on *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350 (Fed. Cir. 2016) and *Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, 848 F.3d 981 (Fed. Cir. 2017) is misplaced. In *Amgen*, the Federal Circuit distinguished those cases because the decisions were based the interpretation of the Markush groups alone “without any reliance on the ‘compromising’ language of the general transition phrase.” *Amgen*, 945 F.3d at 1378. The *Multilayer* and *Shire* cases are not inconsistent with the Court’s holding that the Markush groups in Claims 125 and 132 are closed while the components that compromise the sample are open.

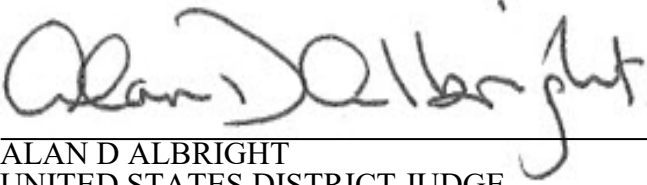
Natera also argues the holding in *Amgen* was based on the claim language “at least one” rather than “comprising.” The Markush groups at issue in *Amgen* recited “at least one binder selected from the group consisting of ...” and “at least one disintegrant selected from the group consisting of ....” *Amgen*, 945 F.3d at 1371. Thus, those Markush groups covered one or more of the recited Markush options but the Markush group in the asserted claims is limited to only one of

the Markush options. While the *Amgen* court discussed both the “at least one” and “comprising” language, the holding applies to claims with “comprising” alone. As the Federal Circuit held, “Amgen’s use of the ‘comprising’ transition phrases reinforces the conclusion that the language of those limitations is best construed not to foreclose such additional binders and disintegrants.” *Id.* at 1379.

For the above reasons, the Markush groups of the asserted claims are closed, but the claims do not exclude a second agent, whether or not the second agent falls within the claimed Markush group. *See id.* (a closed Markush group “does not forbid infringement of the claim if an additional component is present functionally similar to the component identified in the Markush group limitation ...”). Thus, even if the accused products include allantoin and allantoin inhibits cell lysis, the mere presence of allantoin does not result in non-infringement.

For these reasons, the Court **DENIES** Natera’s Motion for Summary Judgement of Non-Infringement (Dkt. 332).

SIGNED this 10th day of January, 2024.



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ALAN D ALBRIGHT  
UNITED STATES DISTRICT JUDGE